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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

June 7, 2004

Ref: 2004-DAL-WL-16

WARNING LETTER

FACSIMILE AND CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bill Swail, President
Peoples Pharmacy, Inc.
3801 South Lamar Blvd., Ste. C
Austin, Texas 78704

Dear Mr. Swail:

On April 14-17, 2003, investigators from the U.S. Food and Drug Administration (FDA) and the Texas State Board of Pharmacy inspected Peoples Pharmacy #1, 4018 North Lamar Blvd., Austin, TX. This inspection revealed that your firm compounds human prescription drugs in various dosage forms and strengths.

As you may be aware, Section 127 of the FDA Modernization Act of 1997 amended the Federal Food, Drug, and Cosmetic Act (the Act) by adding section 503A, which specified certain conditions under which compounded human drugs could be exempt from particular requirements of the Act. In April 2002, however, the United States Supreme Court struck down the commercial speech restrictions in section 503A of the Act as unconstitutional. Accordingly, all of section 503A is now invalid.

As a result, the agency now utilizes its longstanding policy to exercise its enforcement discretion regarding certain types of pharmacy compounding. This policy is articulated in Compliance Policy Guide (CPG), section 460.200, issued on June 7, 2002. The CPG contains factors that the agency considers in deciding whether to exercise its enforcement discretion. One factor is whether a firm is compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application, as required by 21 U.S.C. § 355(i) and 21 CFR Part 312.

The factors listed in the CPG are not intended to be exhaustive, and other factors may also be appropriate for consideration, including factors that indicate that a compounded product may have a potential adverse affect on the public health.

The inspection documented that your firm prepares and distributes 5mg, 10mg, 20mg, 30mg, and 40 mg domperidone capsules for human use.

The agency is concerned with the public health risks associated with the compounding of domperidone. There have been several published reports and case studies of cardiac arrhythmias, cardiac arrest and sudden death in patients receiving an intravenous form of domperidone that has been withdrawn from marketing in several countries. Among other uses, FDA has become aware of the use of domperidone by lactating women to increase breast milk production because of its effect on prolactin levels. While domperidone is approved in several other countries for the treatment of gastric stasis and gastroparesis, domperidone is not approved in any country for enhancing breast milk production in lactating women. In several countries where the oral form of domperidone continues to be marketed, labels for the product note that domperidone is excreted in the breast milk of lactating women and recommend that women taking domperidone avoid breast-feeding. Because of this, FDA recommends that breastfeeding women not use domperidone to increase milk production.

Domperidone is not an active ingredient contained in any FDA-approved drug product. FDA does not sanction its use in pharmacy compounding and will not exercise its enforcement discretion for compounded products containing domperidone.

All products compounded by your firm containing domperidone are drugs within the meaning of section 201(g) of the Act. As they are not generally recognized by qualified experts as safe and effective for their labeled use, the products are new drugs, as defined by section 201(p) of the Act. No approved application pursuant to section 505 of the Act is effective with respect to these products. Accordingly, introduction or delivery for introduction into interstate commerce of these products violates section 505(a) of the Act. These products are also misbranded under section 502(f)(1) of the Act because they do not bear adequate directions for use and they are not exempt from this requirement under 21 CFR § 201.115.

FDA is also very concerned that the injectable drug product betamethasone acetate/betamethasone phosphate is compounded and distributed by your firm without the necessary controls to ensure drug product sterility and potency. These observations were outlined in the Form FDA-483, Inspectional Observations, issued at the conclusion of the inspection. We note that your firm has agreed to correct these deficiencies.

Further, we note that your firm's "Formula File" (a listing of formulations available for compounding), contains formulas for cisapride capsules and cisapride suspension. Another factor that FDA considers in determining whether to exercise its enforcement discretion regarding pharmacy compounding is whether a firm is compounding drugs

that are "versions" of drugs that were withdrawn or removed from the market for safety reasons, as is the case with cisapride. If you are compounding products containing cisapride for human use, FDA will not exercise its enforcement discretion to permit this practice, and you will be violating the Act.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that all drug products compounded and processed by any of your pharmacy locations comply with federal laws and regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in additional regulatory action without further notice. These actions include, but are not limited to, seizure of your products or injunction. Federal agencies are routinely advised of warning letters issued so that they may take this information into account when considering the award of government contracts.

Please notify this office within 15 working days of receipt of this letter of the specific steps that you have taken to correct these violations, including the steps taken to prevent the recurrence of the violations. You should address your reply to this letter to the U. S. Food and Drug Administration, Attention: Jim Lahar, Compliance Officer, at the above address.

Sincerely,

Michael A. Chappell
Director, Dallas District

MAC: JRL